

Claim Amendments

- Please cancel, without prejudice, claims 12 and 28.
- Please amend claims 1, 26, 30 and 31 as indicated in the attached amendment sheet.

Claims 1 and 26, have been restructured to provide a medical electrical lead comprising: 1) the insulative lead body of the electrical leads which are not formed with an active agent, and 2) a polymer overcoating of said lead body providing a tissue-contacting surface and having an active agent; wherein said overcoating is chosen such that said polymer and said active agent are free of micron sized particulates.

Claim 30 has been amended to claim the process of overcoating the medical electrical lead wherein said overcoating is chosen such that said polymer and said active agent are free of micron sized particulates. Claims 31 and 32 have been amended to recite the requirement of independent claim 30 that the overcoating is free of micron size particles.

Support for amendments for adding the overcoating free of micron sized particles is found in the specification and the prior art:

In one embodiment, the polymer of the tissue-contacting surface and an anti-inflammatory agent are intimately mixed either by blending or using a solvent in which they are both soluble (e.g., xylene for silicone and dexamethasone phosphate). This mixture can then be formed into the desired shape and incorporated into the medical device or coated onto an underlying structure of the medical device [Applicants Specification – Page 13, last paragraph]

Alternatively, an overcoating polymer, which may or may not be the same polymer that forms the primary polymer of the tissue-contacting surface, and an anti-inflammatory agent are intimately mixed, either by blending or using a solvent in which they are both soluble, and coated onto the tissue-contacting surface. [Applicants Specification – Page 14, first paragraph]

Applicants specification clearly teaches that an overcoating polymer is either blended or using a solvent which both the polymer and active agent a soluble. This inherently provides that their would not be particulates as described by Helmus, however, applicants have expressly put the physical limitation of not having micron sized particulates in the claims to clarify their polymers from those of Helmus (polymer structures of Helmus being known in the art).